PATENT
Attorney Docket No.: 10123 - 03203

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**
**BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

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| In re Application of: | ) | |
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| **Wise et al.** | ) | |
| | ) | |
| Serial No.: 09/864,488 | ) | Group Art Unit: 3763 |
| | ) | |
| Filed: May 24, 2001 | ) | Examiner: Kevin C. Sirmons |
| | ) | |
| For: ANTI-CLOTTING METHODS AND APPARATUS INDWELLING CATHER TUBES | ) | **Board of Patent Appeals and Interferences** |

Mail Stop: Appeal Brief - Patents
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Alexandria, VA 22313-1450

## APPEAL BRIEF UNDER 37 C.F.R. § 41.37

In support of the Notice of Appeal filed April 17, 2006 and pursuant to 37 C.F.R. § 41.37, appellants present an appeal brief in the above-captioned application.

This is an appeal to the Board of Patent Appeals and Interferences from the Examiner's final rejection of claims 56, 59-66, 68-72 and 74 in the final Office Action dated December 30, 2005 and maintained in the Advisory Action of March 22, 2006. The appealed claims are set forth in the attached Claims Appendix.

1. Real Party in Interest

This application is assigned to Scimed Life Systems, Inc., the real party in interest.

2. Related Appeals and Interferences

There are no other appeals or interferences which would directly affect, be directly affected by, or have a bearing on the instant appeal.

3. Status of the Claims

Claims 56, 59-66, 68-72 and 74 have been finally rejected. Claims 1-54 have been cancelled. Claims 55, 57, 58, 67 and 73 have been withdrawn. Claims 75-79 have been objected to, and claims 80 and 81 have been allowed.

The final rejection of claims 56, 59-66, 68-72 and 74 is being appealed.

4. Status of Amendments

All amendments submitted by the appellants have been entered.

5. Summary of Claimed Subject Matter

The present invention is directed to, in one instance, a system for establishing intermittent fluid communication with the bloodstream comprising a catheter including first and second lumens 20, 24 extending therethrough from a proximal end of the catheter 62 to a distal

end 67 thereof, wherein, when in an operative position, the distal end 67 of the catheter resides within a blood vessel 22. *Specification*, p. 9, ll. 3-12; Fig. 3. The system further includes a first sealing balloon 76 positionable within a distal end of the first lumen 20, so that, when inflated, the first balloon seals the distal end of the first lumen to prevent blood flow thereinto, and a deflation mechanism 70 for deflating the first balloon to reopen the first lumen to blood flow thereinto while the distal end of the catheter remains within the blood vessel. *Id.* at p. 8, ll. 4-7.

In another instance, the present invention is directed to a method of sealing a catheter indwelling within a vessel comprising the acts of advancing a first deflated balloon 76 along a first lumen 24 of the catheter to a position at least partially radially within a distal end thereof, inflating the first balloon 76 to seal the first lumen at the distal end thereof to prevent fluid from entering the distal end of the first lumen and purging the first lumen. *Id.* at p. 9, ll. 3-19; Fig. 3.

In a further instance, the present invention is directed to a method of sealing a catheter indwelling within a vessel comprising the acts of terminating flow along a hollow interior passageway of the catheter, inflating a balloon 76 to seal the hollow interior passageway at a distal end of the catheter to prevent blood in the vessel from entering the hollow interior passageway, deflating the previously inflated balloon 76 to unseal the hollow interior passageway when flow through the hollow interior passageway of the catheter is desired and withdrawing the balloon from the catheter after the deflating act. *Id.*

In yet another instance, the present invention is directed to a system for establishing intermittent fluid communication with the bloodstream comprising a catheter including a lumen 24 extending therethrough from a proximal end of the catheter to a distal end 67 thereof, and, when in an operative position, the distal end of the catheter resides within a blood vessel. The system further includes a balloon 76 which, when inflated, physically contacts and seals the distal end of the lumen to prevent blood flow thereinto, and a deflation mechanism 70 for deflating the balloon to reopen the lumen to blood flow thereinto while the distal end of the catheter remains within the blood vessel. *Id.*

In still another instance, the present invention is directed to a system for establishing intermittent fluid communication with the bloodstream comprising first and second non-concentric catheters 20, 24 each of the first and second catheters including a lumen extending therethrough between proximal and distal ends thereof, and, when in an operative position, the distal ends of the first and second catheters reside within a blood vessel of a patient. The system further includes first and second balloons 76 positionable within distal ends of the first and second catheters, respectively, so that, when inflated, the first and second balloons 76 seals the respective distal ends of the lumens of the first and second catheters to prevent blood flow thereinto, and a deflation mechanism 70 for deflating the balloon to reopen the lumen to blood flow thereinto while the distal end of the catheter remains within the blood vessel. *Id.*; Fig. 7.

6. Grounds of Rejection to be Reviewed on Appeal

I. Whether claims 56, 65-66 and 68-69 are unpatentable under 35 U.S.C. 102(b) as anticipated by U.S. Patent No. 4,564,104 to Fogarty et al. ("Fogarty").

II. Whether claims 59-64 are unpatentable under 35 U.S.C. § 103(a) over Fogarty in view of U.S. Patent No. 5,176,698 to Burns.

III. Whether claims 70-72 and 74 are unpatentable under 35 U.S.C. § 103(a) over U.S. Patent No. 5,092,839 to Kipperman.

7. Argument

I. The Rejection of Claims 56, 65-66 and 68-69 as Unpatentable Under 35 U.S.C. § 102(b) as Anticipated by Fogarty Should be Reversed

Claim 56 recites a system for establishing intermittent fluid communication with the bloodstream comprising "a catheter including first and second lumens extending therethrough from a proximal end of the catheter to a distal end thereof, wherein, when in an operative position, the distal end of the catheter resides within a blood vessel" in combination with "*a first sealing balloon positionable within a distal end of the first lumen, so that, when inflated, the first balloon seals the distal end of the first lumen to prevent blood flow thereinto*" and "a deflation mechanism for deflating the first balloon to reopen the first lumen to blood flow thereinto while the distal end of the catheter remains within the blood vessel."

In contrast, Fogarty describes an apparatus for use in dilating occluded blood vessels having a tube 14 with a closed distal end which extends distally from a distal primary section 18 of a telescopic sheath 16. When the tube 14 is properly positioned as shown in Figs. 2-4 of Fogarty, internal fluid pressure in the tube 14 is increased to expand the tube 14, expanding the lumen of the occluded blood vessel. At no point does bodily fluid from the blood vessel enter the tube 14 or the sheath 16, nor is such entry of blood into the tube 14 or the sheath 16 contemplated or suggested by Fogarty. In fact, Fogarty states that the primary section 18 is proportioned to snugly receive the tube 14. *Fogarty*, col. 3, lines 18-20.

In another embodiment of the apparatus in Fogarty, a hollow tube 22a extends through the tube 14 to a distal open end, allowing for injection of fluid therethrough. *Id.* at col. 3, ll. 13-17. As shown in Fig. 7, the tube 14 circumscribes the hollow tube 22a so that the distal open end of the hollow tube 22a remains open, whether the tube 14 is inflated or deflated. Thus, it is respectfully submitted that Fogarty neither discloses nor suggests "a first sealing balloon positionable within a distal end of the first lumen, so that, when inflated, *the first balloon seals the distal end of the first lumen to prevent blood flow thereinto*," as recited in claim 56, and that the Board should reverse the rejection of this claim which is neither shown nor suggested by Fogarty.

Claim 65 recites limitations substantially similar limitations to those of claim 56 including "a balloon which, when inflated, physically contacts and seals the distal end of the lumen to prevent blood flow thereinto" and "a deflection mechanism for deflating the balloon to

reopen the lumen to blood flow thereinto while the distal end of the catheter remains within the blood vessel." Thus, it is respectfully submitted that claim 65 is allowable for at least the same reasons as claim 56, and that the Board should reverse the rejection of this claim. Because claims 66 and 68-69 depend from, and, therefore include all of the limitations of claim 65, it is respectfully submitted that these claims are also allowable, and that the Board should reverse the rejection of these claims.

II. The Rejection of Claims 59-64 Under 35 U.S.C. § 103(a) Over Fogarty in View of Burns Should be Reversed

Claim 59 recites a method of sealing a catheter indwelling within a vessel comprising the acts of "advancing a first deflated balloon along a first lumen of the catheter to a position at least partially radially within a distal end thereof" in combination with "*inflating the first balloon to seal the first lumen at the distal end thereof to prevent fluid from entering the distal end of the first lumen*" and "purging the first lumen."

As stated above, Fogarty neither discloses nor suggests either "inflating the first balloon to seal the first lumen at the distal end thereof to prevent fluid from entering the distal end of the first lumen" or "purging the first lumen." It is respectfully submitted that Burns does not cure the deficiencies of Fogarty. Specifically, a balloon member 16 in Burns is disposed circumferentially around a distal end opening 47 of a shaft 14 and never seals/opens the distal end opening 47. In fact, the distal end opening 47 is permanently sealed to prevent proximal flow therethrough, only allowing gas from inside the shaft 14 to be expelled from therefrom.

*Burns*, col. 5, ll. 4-10. Thus, it is respectfully submitted that Fogarty and Burns, either alone or in combination, do not disclose or suggest "inflating the first balloon to seal the first lumen at the distal end thereof to prevent fluid from entering the distal end of the first lumen," as recited in claim 59, and that the Board should reverse the rejection of this claim. Because claims 60-63 depend from, and, therefore include all of the limitations of claim 59, it is respectfully submitted that these claims are also allowable, and that the Board should reverse the rejection of these claims.

Claim 64 recites limitations substantially similar to claim 59 including "inflating a balloon to seal the hollow interior passageway at a distal end of the catheter to prevent blood in the vessel from entering the hollow interior passageway." Therefore, for at least the reasons described above with respect to claim 59, it is respectfully submitted that claim 64 is also allowable and that the Board should reverse the rejection of this claim.

III. The Rejection of Claims 70-72 and 74 as Unpatentable Under 35 U.S.C. § 103(a) over Kipperman Should be Reversed

Claim 70 recites a system for establishing intermittent fluid communication with a bloodstream comprising "first and second non-concentric catheters, each of the first and second catheters including a lumen extending therethrough between proximal and distal ends thereof, wherein, when in an operative position, the distal ends of the first and second catheters reside within a blood vessel" in combination with "first and second balloons positionable within distal

ends of the first and second catheters, respectively, so that, when inflated, the first and second balloons seal the respective distal ends of the lumens of the first and second catheters to prevent blood flow thereinto" and "a deflation mechanism for deflating the balloon to reopen the lumen to blood flow thereinto while the distal end of the catheter remains within the blood vessel."

In contrast, a balloon 14 described in Kipperman is used to dislodge a thrombus 32 from an occluded artery and to "shovel" the thrombus 32 into a coronary thrombectomy catheter 11. *Kipperman*, col 4 lines 52-62; Figs. 12-14. The balloon 14 remains inflated during withdrawal of the catheter 11 from the blood vessel to plug the catheter 11, preventing the captured thrombus 32 from entering the blood stream. *Id.* at col. 4, line 63 - col. 5, line 9. Without plugging the catheter 11 with the balloon 14, there would be "the risk of the dislodged thrombus 32 being carried away to the brain or other vital areas...." *Id.* at col. 5, ll. 2-5. Because the balloon 14 of Kipperman must stay inflated to encapsulate the thrombus 32, it is respectfully submitted that Kipperman teaches away from "a deflation mechanism for deflating the balloon to reopen the lumen to blood flow thereinto while the distal end of the catheter remains within the blood vessel," as recited in claim 70.

Furthermore, Figs. 2 and 5 of Kipperman show concentric catheters. In the embodiment of Fig. 2, the thrombectomy apparatus comprises "an outer guide catheter 10 through which a hollow coronary thrombectomy catheter is inserted." *Kipperman*, col. 3, ll. 51-53. Even the alternate embodiment of the apparatus shows concentric catheters as tube 41 extending "over the outer wall 44 throughout the length of the tube 21." *Id.* at col. 4, ll. 16-24.

Thus, it is respectfully submitted that Kipperman teaches away from a system including first and second non-concentric catheters, as recited in claim 70 and that the Board should reverse the rejection of this claim. Because claims 71, 72 and 74 depend from and include all of the limitations of claim 70, it is respectfully submitted that these claims are also allowable and that the Board should reverse the rejection of these claims.

8. Conclusions

For the reasons set forth above, Appellants respectfully request that the Board reverse the final rejections of the claims by the Examiner under 35 U.S.C. §§ 102 and 103 and indicate that claims 56, 59-66, 68-72 and 74 are allowable.

Respectfully submitted,

Date: June 16, 2006

By: _____
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## CLAIMS APPENDIX

56. A system for establishing intermittent fluid communication with a patient's bloodstream, comprising:

a catheter including first and second lumens extending therethrough from a proximal end of the catheter to a distal end thereof, wherein, when in an operative position, the distal end of the catheter resides within a blood vessel of a patient; and

a first sealing balloon positionable within a distal end of the first lumen, so that, when inflated, the first balloon seals the distal end of the first lumen to prevent blood flow thereinto; and

a deflation mechanism for deflating the first balloon to reopen the first lumen to blood flow thereinto while the distal end of the catheter remains within the blood vessel.

59. A method of sealing a catheter indwelling within a vessel of a patient, comprising the acts of:

advancing a first deflated balloon along a first lumen of the catheter to a position at least partially radially within a distal end thereof;

inflating the first balloon to seal the first lumen at the distal end thereof to prevent fluid from entering the distal end of the first lumen; and

purging the first lumen.

60. A method according to claim 59, wherein the first lumen is purged in a proximal-to-distal direction with a suitable liquid under pressure prior to inflating the first balloon.

61. A method according to claim 59, wherein the first lumen is purged after inflating the first balloon using a purging liquid under pressure to temporarily deform and unseal the first balloon.

62. A method according to claim 59, further comprising:

deflating the first balloon to eliminate the occlusion of the first lumen; and

causing one of ingress and egress flow through the first lumen after the first balloon has been deflated.

63. A method according to claim 62, further comprising withdrawing the first balloons along the first lumen after deflating the first balloon and before causing flow through the first lumen.

64. A method of sealing a catheter indwelling within a vessel of a patient comprising the acts of:

terminating flow along a hollow interior passageway of the catheter;

after the terminating act, inflating a balloon to seal the hollow interior passageway at a distal end of the catheter to prevent blood in the vessel from entering the hollow interior passageway;

deflating the previously inflated balloon to unseal the hollow interior passageway when flow through the hollow interior passageway of the catheter is desired; and

withdrawing the balloon from the catheter after the deflating act.

65. A system for establishing intermittent fluid communication with a patient's bloodstream, comprising:

a catheter including a lumen extending therethrough from a proximal end of the catheter to a distal end thereof, wherein, when in an operative position, the distal end of the catheter resides within a blood vessel of a patient; and

a balloon which, when inflated, physically contacts, and seals the distal end of the lumen to prevent blood flow thereinto; and

a deflation mechanism for deflating the balloon to reopen the lumen to blood flow thereinto while the distal end of the catheter remains within the blood vessel.

66. The system according to Claim 65, wherein the balloon is carried near a distal end of an inflation/deflation stem, the stem extending within the lumen between the proximal and distal ends of the catheter.

68. The system according to Claim 66, wherein a seal is interposed between the catheter and the stem within the lumen at the proximal end of the catheter, the stem being selectively displaceable along the lumen through a central opening in the seal.

69. The system according to Claim 65, further comprising a port adjacent the proximal end of the catheter by which a flushing liquid under pressure is selectively displaced proximal-to-distal within the lumen.

70. A system for establishing intermittent fluid communication with a patient's bloodstream, comprising:

first and second non-concentric catheters each of the first and second catheters including a lumen extending therethrough between proximal and distal ends thereof, wherein, when in an operative position, the distal ends of the first a and second catheters reside within a blood vessel of a patient;

first and second balloons positionable within distal ends of the first and second catheters, respectively, so that, when inflated, the first and second balloons the respective distal ends of the lumens of the first and second catheters to prevent blood flow thereinto; and

a deflation mechanism for deflating the balloon to reopen the lumen to blood flow thereinto while the distal end of the catheter remains within the blood vessel.

71. The system according to Claim 70, further comprising a first inflation/deflation stem extending within the lumen of the first catheter and a second inflation/deflation stem extending within the lumen of the second catheter, wherein each of the first and second stems extends for substantially the full length of the first and second catheters, respectively and wherein the first and second balloons are carried near distal ends the first and second stems, respectively.

72. The system according to Claim 71, wherein a contiguous seal is interposed between proximal ends of the first and second catheters and the first and second stems, respectively, within the lumen of the respective one of the first and second catheter, each of the first and second stems being selectively displaceable along the lumen of the respective one of the first and second catheters through a central opening in the corresponding seal.

74. The system according to Claim 70, further comprising a port near the proximal end of each catheter by which a flushing liquid under pressure is selectively displaced proximal-to-distal within the corresponding lumen.

## EVIDENCE APPENDIX

No evidence has been entered or relied upon in the present appeal.

## RELATED PROCEEDING APPENDIX

No decisions have been rendered regarding the present appeal or any proceedings related thereto.

AF ZJW

Attorney Docket No. 10123/03203 (01-535US03)

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| Inventor(s) | : | Wise et al. |
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| For | : | Anti-Clotting Methods and Apparatus for Indwelling Catheter Tubes |
| Group Art Unit: | : | 3763 |
| Examiner | : | Kevin C. Simmons |

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By: Oleg F. Kaplun, (Reg. No. 45,559) Date: June 16, 2006

## TRANSMITTAL

In support to the Notice of Appeal filed April 17, 2006 and the Advisory Action dated March 22, 2006, transmitted herewith please find an Appeal Brief for filing in the above-identified application. Please charge the Credit Card of **Fay Kaplun & Marcin, LLP** in the amount of $500.00 (PTO-Form 2038 is enclosed herewith). The Commissioner is hereby authorized to charge the **Deposit Account of Fay Kaplun & Marcin, LLP NO. 50-1492** for any additional required fees. A copy of this paper is enclosed for that purpose.

Respectfully submitted,

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